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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,418	11/16/2000	David A. Lewin	10716/12	7715

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EXAMINER
ROMEO, DAVID S

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 07/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/715,418	LEWIN ET AL.	
	Examiner	Art Unit	
	David Romeo ~~Elizabeth C. Kommerer~~, Ph.D.	~~1646~~ 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-40* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 29 and 32, drawn to polypeptides and compositions or kits comprising same, classified in class 530, subclass 350, for example.

II. Claims 5-14, drawn to nucleic acids, and vectors or host cells comprising same, classified in class 536, subclass 23.1, for example.

III. Claims 15-18, 31 and 34, drawn to antibodies and compositions comprising same, classified in class 530, subclass 387.1, for example.

IV. Claim 19, drawn to method of detecting nucleic acid, classified in class 435, subclass 6, for example.

V. Claim 20, drawn to method of identifying a polypeptide binding agent, classification dependent upon structure of agent.

VI. Claim 21, drawn to method of identifying a potential therapeutic agent, classification dependent upon structure of agent.

VII. Claim 22, drawn to method for modulating activity of a polypeptide comprising exposing to an agent, classification dependent upon structure of agent.

VIII. Claims 23, 24 and 39, drawn to method of therapeutically administering polypeptide, classified in class 514, subclass 2, for example.

IX. Claims 25, 26, 30 and 33, drawn to gene therapy compositions and methods, classified in class 514, subclass 44, for example.

X. Claims 27, 28 and 40, drawn to methods of therapeutically administering antibody, classified in class 424, subclass 130.1, for example.

XI. Claims 35 and 36, drawn to methods of screening for a modulator of activity or latency or predisposition to a pathology comprising exposing a polypeptide to an agent, classification dependent upon structure of agent.

XII. Claim 37, drawn to method for determining presence or predisposition to disease comprising measuring expression of polypeptide, classification dependent upon how expression is measured.

XIII. Claim 38, drawn to method for determining presence or predisposition to disease comprising measuring expression of nucleic acid, classified in class 435, subclass 6, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and each of V, VI, VII, VIII, XI and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Invention I can be used to isolate receptors.

Inventions II and each of IV, IX and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be

shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of Invention II can be used to express protein recombinantly in vitro.

Inventions III and X and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies of Invention III can be used to label or isolate the polypeptides they bind.

Inventions V and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the method can be used to identify binding agents other than antibodies, such as small organic molecules.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to <u>different</u> products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Groups I-III and IX are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Further, the protein of Group I can be

prepared by processes which are materially different from recombinant DNA expression of Group II, such as by chemical synthesis, or by isolation and purification from natural sources. Additionally, the DNA of Group II can be used other than to make the protein of Group I, such in gene therapy or as a probe in nucleic acid hybridization assays. The protein of Group I can be used in materially different methods other than to make the antibody of Group III, such as in therapeutic or diagnostic methods (e.g., in screening). Although the antibody of Group III can be used to obtain the DNA of Group II, it can also be used in materially different methods, such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography), or therapeutic methods. The gene therapy compositions of Group IX require the nucleic acids of Group II, however, the nucleic acids can be sued in compositions and methods unrelated to gene therapy, such as probes in hybridization analysis, or templates for recombinant protein expression in vitro. The gene therapy compositions of Group IX are independent and distinct from the proteins of Group I and the antibodies of Group III, because neither the antibodies nr the proteins are required to make the gene therapy compositions.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups IV-XIII are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention IV requires search and consideration of hybridization analysis, which is not required by any of the other groups. Invention V

requires search and consideration of screening for protein binding agents, which is not required by any of the other groups. Invention VI requires search and consideration of screening for therapeutic agents, which is not required by any of the other groups. Invention VII requires search and consideration of screening for protein modulators, which is not required by any of the other groups. Invention VIII requires search and consideration of therapeutic effects of proteins, which is not required by any of the other groups. Invention IX requires search and consideration of therapeutic effects of nucleic acids, which is not required by any of the other groups. Invention X requires search and consideration of therapeutic effects of antibodies, which is not required by any of the other groups. Invention XI requires search and consideration of screening for modulators that are linked to pathology, which is not required by any of the other groups. Invention XII requires search and consideration of pathology diagnosis involving polypeptide measurement, which is not required by any of the other groups. Invention XIII requires search and consideration of pathology diagnosis involving nucleic acid measurement, which is not required by any of the other groups. Therefore, a search and examination of all of the methods in one patent application would result in an undue burden, since the searches for the methods are not co-extensive, the classification is different, and the subject matter is divergent.

The remaining pairs of Inventions are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the Inventions are not disclosed as

capable of use together and have different modes of operation. Specifically, the method of each remaining Invention pair does not require the product of each remaining Invention pair.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and/or different classification, restriction for examination purposes as indicated is proper.

FURTHERMORE, restriction to one of the following inventions is required under 35 U.S.C. 121:

A. The inventions as they pertain to the polypeptide of SEQ ID NO: 3 (or nucleic acids encoding same)

B. The inventions as they pertain to the polypeptide of SEQ ID NO: 6 (or nucleic acids encoding same)

The inventions are distinct, each from the other because of the following reasons: Each sequence requires a separate search of the literature and sequence databases. A search and examination of an Invention as it pertains to both sequences would therefore present the examiner with an undue search burden. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and separate search requirements, restriction for examination purposes as indicated is proper. Applicant is

advised that the restriction requirement between SEQ ID NOS: 3 and 6 is not a requirement for election of species. Rather, it is a second layer of restriction requirement between independent and distinct Inventions. In order to be fully responsive, Applicant must elect one from I-XIII and one from A-B.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Romeo, Ph.D., whose telephone number is (703) 305-4050.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, Ph.D., can be reached on (703) 308-4623. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER

ECK
July 1, 2002